

Application No.: 10/014,909
Art Unit: 1645

Attorney Docket No. 19641.01
Confirmation No. 4215

REMARKS

By the present amendment, Applicant has cancelled Claims 1-40 , and added Claims 41-46. Claims 41-46 remain pending in the present application. Claim 41 is an independent claim.

Applicant appreciates the courtesies extended to Applicant's representative during the personal interview held October 10, 2003. The present response summarizes the substance of the interview. At the interview, proposed new Claims 41-46 were presented for discussion. Proposed independent Claim 41 set forth an oral composition for oral administration comprising an extract of *Heliopsis longipes* root in an amount of about 0.5 to about 1000 mg/ml and an oral carrier. The oral composition was set forth as being in a form selected from the group consisting of a powder, a gel, a paste, a tablet, a capsule, a gum, a lozenge, an aerosol, and a liquid. Dependent Claims 42-46 set forth specific formulations of the oral composition. Arguments were advanced that the compositions defined by the proposed claims were patentably distinguishable over Romero et al., the applied prior art of record. Applicant's representative pointed out that Romero et al. discloses the antibacterial, insecticidal, and toxicological effects of the total alcoholic extract of *Heliopsis longipes* and not a composition which includes the extract and an oral carrier. Furthermore, the studies disclosed in Romero et al. do not teach or suggest oral administration of the extract for Applicant's disclosed purposes. The Examiners agreed that Romero et al. does not teach a composition which includes the extract of *Heliopsis longipes* and an oral carrier. The Examiners pointed out, however, that Romero et al. does teach a composition which includes the extract in a solution. As

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such, the Examiners suggested amending the claims to further define the liquid form of the inventive composition by adding the terminology “a glycerine and sorbitol containing” before “liquid” in the proposed independent claim. The Examiners also suggested additional amendments to the proposed claims to further distinguish the present invention from the prior art. Specifically, the Examiners suggested including the acceptable percentage by weight of the extract in relation to the composition and to add the limitation that the gum form of the composition is chewable. The Examiners further suggested removing the term “carrier” from each of the dependent claims and removing all trademark names, abbreviations, and terms in parenthesis. The Examiners held that while a new search would have to be conducted to determine the patentability of new independent Claim 41, the proposed claims, if amended to include the limitations suggested by the Examiner, would appear to be allowable.

Claims 30-40 were held withdrawn from consideration by the Examiner as being directed to a non-elected invention. Accordingly, it is proposed herein that the instant claims be canceled. However, it should be noted that under the provisions of 35 U.S.C. § 121 Applicant reserves the right to file a divisional application directed to the non-elected subject matter.

In the recent Office Action the Examiner rejected Claims 1-29 under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 26 was objected to under 37 CFR 1.75 (c), as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claims 1-29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Romero et al..

The cancellation of claims 1-40 and the introduction of claims 41-46 by the present amendment should serve to obviate the rejection based on indefiniteness and the prior art grounds of rejection of record. The newly introduced terms are devoid of the terms “desirable sensations”, “relative to the composition”, “a wet component and a dry component”, a “wet component and a dry component”, and “and any other...to the oral cavity.” Also, the claims have been amended in accordance with the Examiners’ suggestion to specify that the composition can take the form of a powder or a paste. Consequently, Applicant respectfully submits that newly presented Claims 41-46 meet the specific requirements of 35 U.S.C. § 112, second paragraph.

Regarding the prior art grounds of rejection, Applicant will advance arguments hereinbelow to illustrate the manner in which the presently claimed invention is patentably distinguishable from the cited and applied prior art. Reconsideration is respectfully requested.

Claims 41-46 have been newly introduced to more particularly define Applicant’s invention in light of the prior art of record. New independent Claim 41 defines an herbal composition for oral administration comprising an extract of *Heliopsis longipes* root in an amount of about 0.01% - 10% by weight of the composition and an oral carrier. Claim 41 further sets forth that the composition must provide an amount of about .5 mg/ml-1000 mg/ml of the extract per effective dosage and be in a form selected from the group consisting of a powder, a gel, a paste, a tablet, a capsule, a chewable gum, a lozenge, an aerosol, and a liquid which contains at least one flavoring agent. New dependent Claim 42 sets forth that the composition includes about 1%-2% by weight of the *Heliopsis longipes* root extract and the liquid includes about 48%

by weight distilled water, about 20% by weight glycerine, about 30% by weight sorbitol powder, about 0.1% by weight potassium sorbate, about 0.1% by weight sodium benzoate, and about 0.2% by weight citric acid powder. New dependent Claim 43 sets forth that the composition includes about 1%-2% by weight of the *Heliopsis longipes* root extract and the liquid carrier includes about 11% by weight distilled water, about 11% by weight glycerine, about 76% by weight sorbitol solution, and about 0.3%-0.5% by weight peppermint flavor. New dependent Claim 44 sets forth that the composition includes about 3% by weight of the *Heliopsis longipes* root extract and the gum includes about 28% by weight gum base, about 17% by weight polysorbate, about 0.25% by weight acesulfame K, about 0.5% by weight glycerine, about 47% by weight sorbitol, about 2% by weight mannitol, and about 2% by weight peppermint flavoring. New dependent Claim 45 sets forth that the composition includes about 3% by weight of the *Heliopsis longipes* root extract and the gum includes about 50% by weight gum base, about 16% by weight polysorbate, about 0.25% by weight acesulfame K, about 1.0% by weight glycerine, about 24.00% by weight sorbitol, about 2% by weight mannitol, and about 3% by weight peppermint flavoring. New dependent Claim 46 sets forth that the composition includes about 1-2% by weight of the *Heliopsis longipes* root extract and the tablet includes about 98% by weight sorbitol powder, about 0.4%-0.5% by weight peppermint flavoring, and about 1.0% by weight magnesium stearate.

Basis for the newly presented claims and particularly the amounts of the extract and each ingredient in the composition as stated in the claims can be found on page 7, line 12, and Tables 1-5 on pages 19-30 of Applicant's original specification. Basis for the particular forms of the composition can be found on page

15, lines 1-3. Basis for “a flavoring agent” in the composition can be found on page 15, line 10. No new matter is involved by the presentation of new Claims 41-46 since the limitations set forth by the instant claims find sufficient support in Applicant’s disclosure.

Applicant notes that Romero et al. discloses an alcoholic extract of *Heliopsis longipes*. However, Romero et al. discloses the antibacterial, insecticidal and toxicological effects of the total alcoholic extract of *Heliopsis longipes*. Applicant respectfully points out that Romero et al. does not teach an herbal composition which includes an extract of *Heliopsis longipes* and an oral carrier as presently claimed. In fact, the studies described in Romero et al. do not even suggest oral administration of the extract of *Heliopsis longipes*. Consequently, Applicant contends that there appears no disclosure or suggestion in the prior art that would enable one of ordinary skill in the art to arrive at the presently claimed composition. Applicant has considered, however, the suggestions given by the Examiner during the interview held on October 10, 2003 regarding amendment of the proposed new claims. Applicants believe that the terminology “glycerine and sorbitol containing” suggested by the Examiner to further define the liquid forms of the claimed composition so as to further distinguish the present invention from Romero et al. is unnecessarily limiting. Applicant has instead specified that the liquid forms of the claimed composition contain “flavoring agents”, as disclosed on page 15, line 10 of the specification, as such a composition is clearly not disclosed in Romero et al.. Applicant has amended the claims in all other respects, in accordance with the Examiners’ suggestions.

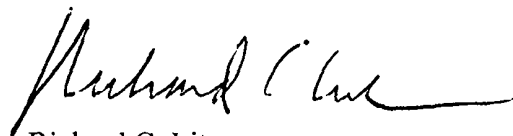
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The claims in this application have been revised to more particularly define applicants' unique construction in view of the prior art of record. Reconsideration of the claims in light of the amendments and for the following reasons is respectfully requested.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance. If such is not the case, the Examiner is requested to kindly contact the undersigned in an effort to satisfactorily conclude the prosecution of this application.

Respectfully submitted,



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